toring was defined as receipt of ≥1 serum ferritin test after 10th unit. ICT-eligibility was defined as ≥2 serum ferritin tests ≥1,000 μg/L or ≥20 units transfused. ICT treatment was defined as ≥1 prescription/administration for deferasirox or deferoxamine. Kaplan-Meier and Cox proportional hazards regression methods were used to compare overall survival. **RESULTS:** A total of 163 patients were included; 58.3% and 30.1% received ≥20 and ≥30 RBC units, respectively. A total of 50.3% had leukemia and 20.2% had myelodysplastic syndrome as the underlying disease. A total of 44.8%, 53.7% and 67.3% of patients receiving ≥10, ≥20 and ≥30 RBC units, respectively, were monitored for TIO. Compared to unmonitored patients, TIO-monitored patients had significantly longer median OS (16.13 vs. 2.30 months; log-rank p-value<0.001) even after confounder adjustment (hazards ratio 0.271; p-value<0.001). Among 99 ICT-eligible patients, 9% received ICT; 8 (88.9%) received deferasirox. Median OS for ICT-treated patients and untreated patients was 9.48 and 7.16 months, respectively (log-rank p-value=0.593). **CONCLUSIONS:** To conclude, TIO monitoring after 10 RBC units may be associated with survival benefits, but <50% of patients receiving ≥10 transfusions were monitored for TIO. Clinical benefits of chelating cancer patients have not been established and additional studies are necessary to ascertain the impact of TIO and chelation utility among cancer patients.

PSY7

A NOVEL MECHANISM OF CAPTURING POST-MARKETING SAFETY INFORMATION ON RECOMBINANT FACTOR VIIA (RFVIIA) IN THE RARE DISORDER ACQUIRED HEMOPHILIA: THE ACQUIRED HEMOPHILIA SURVEILLANCE (AHS) PROJECT

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OBJECTIVES: Acquired hemophilia (AH) is a rare disorder (1 per 1.3 million) characterized by auto-antibodies to factor VIII. AH is characterized by life-threatening bleeding and high mortality. Recombinant factor VIIa (rFVIIa) received FDA approval for treatment of AH in 2006. As part of the post-approval commitment, Novo Nordisk agreed to use a society-owned research registry to monitor treatment of AH bleeding episodes. This required IRB approval and informed consent. For sites with few patients and/or limited research staff, the registry was not a feasible option **METHODS:** An alternative web-based, IRB-exempt reporting method, Acquired Hemophilia Surveillance (AHS, www.novosevensurveillance.com), was established to collect data on rFVIIa use in AH and associated adverse events under the HIPAA safety surveillance waiver. **RESULTS:** From April 2008-January 2011, 32 reporters submitted 80 case reports (32 male/48 female). The mean age was 65 years (range 16-97). Common associated conditions were autoimmune disorders (32 patients), malignancy (6 patients) and post-partum state (5 patients). On average, 5 discrete bleeding events per patient (range 0-100) were reported; 75 case reports described bleeding as spontaneous (88%), surgical (16%), and/or related to a procedure (15%). No bypassing agent was reported to have been used in 17 (21%). rFVIIa was used in 50 (63%), the majority of which were first-line (39, 78%). AH was reported to have been "resolved" in 44 (55%), "not resolved" in 19 (24%), and "unsure" in 16 (20%); mean(median) time to resolution was 7.2(2) months (range 1-52). There were no reported deaths. None of the 50 rFVIIa-treated cases suffered an adverse or thrombotic event (AE). **CONCLUSIONS:** AHS provides an innovative approach for hemophilia treatment centers and hematology/oncology practices to capture basic safety surveillance data for patients with Acquired Hemophilia. The AHS project provides additional information about AH treatment, and reaffirms the safety of rFVIIa and the low rate of thrombotic complications.

Systemic Disorders/Conditions – Cost Studies

PSY8

DIRECT AND INDIRECT COSTS OF PRIVATELY-INSURED PATIENTS TREATED WITH OXYMORPHONE EXTENDED-RELEASE OR OXYCODONE CONTROLLED-RELEASE TABLETS

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OBJECTIVES: Compare costs of privately-insured oxymorphone extended-release tablet ("oxymorphone") users with those of oxycodone controlled-release tablet ("oxycodone") users, from an employer's perspective. **METHODS:** Patients, ages 18+, with ≥1 claim for oxymorphone/oxycodone during Q2:2006-Q4:2009 were identified in de-identified private payer claims data and observed from the first such claim ("index date") until the earliest of: use of comparator drug; end of continuous eligibility; or 12 months ("study period"). Continuous eligibility was required throughout a 6-month baseline period and ≥1 month after the index date. Patients with claims for any formulation (extended-release or otherwise) of the comparator drug during the first 30 days of the study period were excluded, as were patients pregnant during the baseline/study periods. Study period risk-adjusted costs were estimated per patient-month using generalized estimating equations controlling for baseline demographics, resource use, and costs. Medical/drug (direct) costs paid by private insurers were reported for patients ages 18-64 (N = 8,354) and 65+ (N = 3,515) as well as subsets of each without cancer during the baseline/study periods (N = 7,090 and N = 2,444, respectively). Medically-related absenteeism and disability (indirect) costs were reported for all employees, ages 18-64, (N = 1,313) and employees without cancer (N = 1,146). Bias-corrected bootstrapping was used to compare third-party payer costs. **RESULTS:** Oxymorphone users, ages 18-64, had lower drug costs ($693 vs. $763, p=0.0035) and similar medical costs ($1,875 vs. $1,976, p=0.3570) per patient-month compared with oxycodone users. Indirect costs were not different ($662 vs. $670, p=0.9370). Oxymorphone users, ages 65+, had similar Medicare supplemental drug costs ($533 vs. $588, p=0.0840) and significantly lower medical costs ($459 vs. $747, p<0.0001). Results were comparable for the subsets without cancer. **CONCLUSIONS:** After controlling for baseline characteristics, real-world evidence suggests that, from an employer's perspective, oxymorphone users may incur lower monthly direct costs than oxycodone users.

PSY9

HEALTH CONSEQUENCES AND COSTS OF TACHOSIL® AS HAEMOSTATIC TREATMENT IN LIVER SURGERY VERSUS TISSUCOL®: A RETROSPECTIVE OBSERVATIONAL COHORT STUDY

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OBJECTIVES: The objective of this study was to compare the effectiveness and costs of TachoSil® carrier-bound collagen sponges versus Tissucol® fibrin glue in patients undergoing liver surgery in current medical practice. **METHODS:** A retrospective observational cohort study was carried out including 244 patients (128 in TachoSil® group and 116 in Tissucol® group) that underwent a liver surgery a university hospital. Data on demographics, medical background, effectiveness, resource consumption and complications were obtained by reviewing patients' medical records. Unit costs were obtained from financial hospital records and drug costs from the Spanish health authorities. Collection of patient data took place from definitive surgery until hospital discharge using a hospital's perspective. Variables collected to estimate costs and effectiveness were haemostatic drugs, surgical time, drainage, blood transfusions and hospitalisation days. Research outcomes were presented as the differences in effectiveness measures and costs for the collected variables using statistical analysis (p<0.05). **RESULTS:** With TachoSil® significantly less patients required a drainage (12.5% vs. 52.6%, p<0.001) and patients were hospitalized for a minor number of days (median 6 vs. 8 days, p=0.00013). No statistical differences between both groups were observed in the rest of the effectiveness data pre- and postoperative. The TachoSil® group showed significant lower mean costs with respect to haemostatic drugs (mean [SD] euro, 974€ [787€] vs. 987€ [384€], p=0.03) and drainage (3€ [7€] vs. 12€ [11€], p=0.00). No significant differences in other costs between both treatments were reported. **CONCLUSIONS:** TachoSil® showed to reduce drainage and hospitalisation days. However no significant lower total costs for the TachoSil® group (10,212€ [8,197€]) vs. the Tissucol® group (10,224€ [7,394€]) could be demonstrated.

PSY10

COST ANALYSIS OF ANEMIA TREATMENT WITH ERYTHROPOIESES-STIMULATING AGENTS (ESAS) IN CANCER PATIENTS RECEIVING CHEMOTHERAPY: A MULTICOUNTRY APPROACH

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OBJECTIVES: Spaepen et al. (the Oncologist 2008;13:596–607) published a cost-analysis comparing darbepoetin alfa (DARB), epoetin alfa (EPO-A) and epoetin beta (EPO-B) in the treatment of chemotherapy-induced anemia, using propensity score matching. The study was performed using the IMS Hospital Disease Database, a longitudinal database unique to Belgium containing individual patient/admission-level data on diagnoses, procedures, and pharmaceuticals. Given the limited availability of other databases reporting the same level of information in other European countries, the objectives of this study were to assess the applicability of the Belgian analysis, and to estimate differences in costs between ESAs in Austria, Italy, Portugal, and Spain. **METHODS:** To adapt the analysis, costs were replaced with country-specific costs and discrepancies in epidemiology and treatment patterns were examined. Adjusting for country discrepancies, costs were analyzed using a mixed-effects model stratifying for propensity score quintiles as in Spaepen 2008. Sources included Eurostat, national cancer registries, IMS sales data, and reimbursement and treatment guidelines for procedures and drugs. **RESULTS:** All populations were comparable to Belgium in terms of age, gender, ESA use, and blood transfusions. Adjusting for chemotherapy use and tumor-specific cancer incidence, total costs (Euro, 2010) with DARB were 22-26% lower compared to EPO-A and 20-35% lower compared to EPO-B. Anemia-related costs were lowest for DARB €2,585±154, EPO-A €3,102±99, EPO-B €2,969±166 in Austria; DARB €3,144±211, EPO-A €5,049±119, EPO-B €3,656±230 in Italy; DARB €2,153±117, EPO-A €2,446±63, EPO-B €2,654±124 in Portugal; and DARB €2,378±143, EPO-A €3,349±75, EPO-B €2,857±153 in Spain. **CONCLUSIONS:** Total and anemia-related costs were lowest in patients receiving DARB compared to EPO-A or EPO-B in all countries. Although it was not possible to account for all differences among countries, the findings are in line with those from the Belgian analysis, and demonstrate the feasibility of adapting such data to other settings accounting for patient characteristics and treatment costs.

PSY11

BURDEN OF ILLNESS IN FIBROMYALGIA SYNDROME: THE PATIENTS' PERSPECTIVES

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